EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2018	SWG support for IRIS
	Base Option Period Number 4	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2017 To 10/31/2018

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2018		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Christine Cai (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8517 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 4-07

TITLE: Dose-Response and Quantitative Analysis Support

Principal Section & Paragraph of SOW: A.1 and B.1,2,5

PERIOD OF PERFORMANCE: November 1, 2017 – October 31, 2018

I. PURPOSE

NOTE: This work assignment is a follow-on to work performed in the Year 3 Option Period under Work Assignment 3-07. The work continues from Task 1 through Task 7 during this Year 4 Option Period under Work Assignment 4-07. We expect work to be initiated for other chemicals in the Year 4 Option Period. This WA is intended to support a limited LOE (around 100-300 hours) on IRIS chemicals as the need arises. IRIS often requires short-term work and quick-response work to revise or amend analyses for specific chemicals, or to initiate exploratory work on a new chemical. Thus all Tasks are carried over from the Year 3 Option Period, to be applied, as needed, for short-term work on a new chemical. This WA is not intended to be a substitute for a chemical-specific WA that supports long-term (1-3 years) work for an IRIS chemical assessment.

The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of Dose-Response and Quantitative Analyses in Support of IRIS. More specifically, this work assignment will continue to provide dose-response analyses, statistical analyses, and other quantitative analyses and research as identified in the contract performance work statement, Sections A(1) and B(1,2, and 5). Data entry and data QA, and data management will be a part of these tasks. Reporting of results in tables of standard IRIS formats will be a part of these tasks.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for noncancer health effects resulting from oral exposure (the RfD), the reference concentration for noncancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughput and decreased effort for assembling and reporting information for IRIS assessments.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this PWS

The contractor shall provide personnel who are proficient with the software tools DRAGON, WIZARD, Microsoft Access, Microsoft Excel, and knowledgeable regarding dosimetric conversions. BMDS (Benchmark Dose Software (http://www.epa.gov/ncea/bmds) is the primary software tool used by IRIS for dose-response modeling, and it is used by DRAGON and WIZARD to conduct dose-response modeling. Therefore, the contractor shall provide personnel who are already experienced with benchmark dose modeling, the use of BMDS, and the formats of BMDS auxiliary files (*.(d),*.dax, *.ssn, *.opt).

Under this PWS, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will specify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (enumerated below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager.

Agency guidance will be applied and exceptions to such guidance will be clearly noted. Agency guidance should be used: (a) to determine the suitability of studies and data used; (b) to guide the preparation of data and the adjustment of doses or concentrations for intermittent and time-varying exposures and less-than-lifetime exposures; (c) to guide the conduct of dose-response modeling and model selection; (d) to guide the development of RfC/RfD values, cancer slope factors, and all other subject matter included in Chapters 2 of a Toxicological Review.

The work shall be conducted so as to be consistent with EPA's Benchmark Dose Technical Guidance Document and other relevant EPA guidelines (e.g., guidelines for carcinogen risk assessment, neurotoxicity, reproductive toxicity, developmental toxicity, and inhalation dosimetry (see documents at http://www.epa.gov/iris/backgrd.html). Quantitative dose-response analyses shall be conducted and reported according to the Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS, to be provided by EPA. If any exceptions to the foregoing guidance and checklist are required for an analysis, they should be noted and explained.

Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]). The contractor shall use the most recent issue of BMDS (BMDS 2.x) for dose-response analyses, where this is feasible and efficient; otherwise, the contractor shall use the latest versions of BMDS executable 'modules' (e.g., multistage.exe) if the latest GUI is not used [these modules are installed with BMDS 2.x].

Input data and BMDS accessory files developed under this Task for the various dose-response analyses shall be delivered. This includes spreadsheets, input files to the BMDS Wizard, and accessory files used and produced by BMDS (e.g., BMDS related files: *.(d), *.set, *.dax, *.opt, *.ssn, *.out, *.002, *.plt, *.emf, and Excel export files from BMDS2). These materials will be organized in subdirectories or by file names so as to distinguish cancer and noncancer effects, exposure routes (inhalation, diet, drinking water), and continuous vs. dichotomous (quantal) responses. These files shall be named or described (e.g., in a Read_Me.txt file or other document) or otherwise organized sufficiently that the data sets and endpoints are recognizable. These

materials will be transmitted in electronic form, e.g., by email in a ZIP file or delivered physically on a CDROM.

The contactor shall develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contactor will provide access to this internal documentation upon request by the EPA WAM (Work Assignment Manager) or EPA Project Officer.

Task 1: Quality Assurance Project Plan (QAPP) and Work Plan

The contractor shall develop both a Work Plan and a quality assurance project plan (QAPP) for this project. These shall state that the QAPP will be observed during the conduct of this work assignment. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP and Work Plan
Due Date: 15 days after issuance of this Performance Work Statement (PWS).

Task 2. Data Entry and Data QA

The contractor shall review data sources to identify data for each endpoint, enter the data into an electronic medium (if not already provided in this form), and verify the data. All data shall be verified as correctly entered from the source. Source publications will usually be accessed using EPA's HERO database.

The contactor is not responsible for verifying secondary data quality for studies and endpoints identified by the EPA WAM unless required to do so in the written Technical Direction pertaining to a specific request.

The contactor will provide, to the EPA WAM, spreadsheets that indicate the source of the individual data element from a study by reference to the page, table, figure, footnote, etc., from the original report being cited. Data will be entered in the units provided in the original paper, with any necessary transformations explicitly performed in the spreadsheet. Units conversions and adjustments for intermittent or non-constant exposure shall be documented explicitly for each data set, with comments as needed. Possible cases of systematic differences in survival between dose groups (typically, lower survival in high dose groups) will be 'flagged'.

When a request involves multiple studies, data will be assembled and organized in either the BMDS WIZARD or in DRAGON, unless the contractor and the EPA WAM agree not to do so.

Deliverables: Notification of completion to EPA WAM by email or telephone. As necessary, questions and problems regarding data will be delivered, with proposed methods of resolution.
Data will be delivered after task 2 completion only if specifically requested (usually the data will be delivered with results of benchmark dose analyses under the Tasks that follow this one).

Due Dates: To be specified either in written technical direction after consultation with the contractor, or, if not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12 distinct endpoints, or (c) one working day for every 8 distinct studies.

Task 3: Noncancer Data Analysis and Benchmark Dose Modeling

Under this task, the contractor will evaluate noncancer data sets for dose-response modeling in a manner consistent with EPA's Benchmark Dose Technical Guidance Document and Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS. The contractor will consult with the EPA WAM as to potential problems with particular experiments and data sets. Prior to modeling data, the contractor will perform any necessary dosimetric adjustments and/or conversions, select appropriate benchmark responses (BMRs) for each endpoint, identify important or unusual statistical issues, and flag data not amenable to benchmark dose modeling. Additionally, the contractor will perform data verification and documentation as outlined in Task 2 prior to dose-response modeling.

To facilitate comparison of multiple candidate PODs, summary results for BMDs, BMDLs, NOAELs and LOAELs will be reported in terms of Human-Equivalent Dose or Concentration (HED/HEC). For chronic and subchronic oral (ingestion) exposures (specifically excluding developmental and short-term studies), a $BW^{3/4}$ default animal-human conversion will be made. Reporting units will be mg/kg-day for oral exposure and either ppm or mg/m^3 for inhalation exposure. RfDs will be reported in mg/kg-day and RfCs will be reported in mg/m^3.

The contractor will model data amenable to benchmark dose modeling using EPA's BMDS2.x. Results will be summarized in tables that report key statistics for model goodness of fit (AIC, p-value for goodness of fit, degrees of freedom for the Chi-square test, and largest scaled Chi-square residual). Based on these results along with considerations of biological relevance, the contractor will identify candidate data sets, endpoints, and models that could be used as a basis for a POD for both ingestion and inhalation exposure routes, as the data permit. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

Deliverable:	spreadsheets holding input data; output (analysis) results by data set with recommended models; summary tables showing key results for selected models for the various datasets (endpoints) by exposure route
Due Date:	7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data Revisions – dates to be specified in written technical direction

Task 4: Cancer data analysis and dose-response modeling

Under this task, the contractor will review the study reports identified by the EPA WAM to identify data sets on cancer incidence amenable to analysis of individual tumor sites. For both ingestion and inhalation exposure routes, as the data permit, cancer data amenable to benchmark dose modeling will be prepared and verified as outlined in Task 2.

The contractor will also identify studies amenable to modeling risk from multiple tumors per animal (when data exists for multiple tumor sites in one study for one sex of one rodent strain, EPA may request an analysis of risk from multiple tumors using the MS_COMBO program or using the "multi-tumor" option of BMDS).

Individual tumor data will be fitted using the 'multistage cancer model' of BMDS (with coefficients constrained to be non-negative) and other models as directed by EPA. Multistage model order selection will be based upon a minimum AIC criterion unless otherwise specified in writing.

After conducting BMDS modeling, the contractor will identify those data sets, endpoints, and models (i.e., orders of the multistage model) that could be used as a basis for unit risk/cancer slope factor. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

Deliverable: spreadsheets holding input data; output (analysis) results by data set with recommended models; summary tables showing key results for selected models for the various datasets (endpoints) by exposure route

Due Date: 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
Revisions – dates to be specified in written technical direction

Task 5: Time-to-Tumor Analysis

The contractor may be requested to review cancer bioassay studies (provided by the EPA WAM) to identify and propose those for which time-to-tumor analysis may need to be applied, or such studies may be identified by the EPA WAM. Time-to-tumor analysis would need to be applied if survival differs substantially among the dose groups.

The contractor will use the "MSW" program for time-to-tumor analysis and will report any failures of the MSW program to solve the BMDL. If this occurs, the program "ToxRisk" (version 5.3) will be used to obtain a BMDL. Subsequently, parameter estimates and BMD resulting from MSW and ToxRisk will be compared to determine similarity. The contractor will also call attention to any instances of parameter estimates on a boundary. Where higher-order coefficients are nonzero, estimates will be presented for all model orders between 1 and the number of dose groups less 1. The EPA WAM may request a conventional BMDS cancer-model analysis based on poly-3 weights applied to the individual animal data, as an alternative to time-to-tumor modeling.

Deliverables: input and output files used/produced by software to fulfill this task (text files and/or spreadsheets); a report with tables summarizing the data, data sources, and results, suitable for inclusion in an Appendix to a Toxicological Review

Due Date: to be specified in written technical direction. EPA will not require completion of more than 6 data sets per work day (to include data entry and QA, data analysis, and reporting) except by prior agreement with the contractor

Task 6: Prepare Draft Materials for IRIS Toxicological Reviews

The contractor, when requested in a technical directive, shall prepare draft portions of an IRIS Toxicological Review, relevant to dose-response or quantitative analyses conducted under other tasks herein, and following the style of the IRIS template for Toxicological Reviews (to be provided by EPA). Drafts may include Evidence Tables, Study Summaries, exposure-response arrays, dose-response modeling, selection of an oral reference dose (RfD), inhalation reference concentration (RfC), cancer modeling (including derivation of a

cancer slope factor and inhalation unit risk), Chapter 2 text and tables, Appendix materials, and related narratives. EPA may also request various types of graphical displays of data.

Deliverables and Due Dates:

Drafts with supporting materials, date to be specified in written technical direction.
Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.
Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

Task 7. Study and Endpoint Screening and Selection for Hazard ID and Dose-Response Analysis

This task may require:

- review of studies for adequacy to support inferences about toxicity and carcinogenicity, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA
- review of studies to support dose-response analysis, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA
- preparation of "evidence tables" in the current IRIS format or new formats
- other tabulations of studies using a layout provided by EPA or proposed by the contractor and confirmed by EPA, and computations needed to calculate results for such tabulations
- graphical presentations comparing studies and endpoints quantitatively and qualitatively, including but not limited to exposure-response arrays and forest plots, and including computations needed to calculate results for such plots
- graphical displays of data, statistics, estimates and endpoints

If so requested, the contractor will document in such tables the preliminary decisions (including rationales) about critical endpoints, to include (if so directed) MOA, sensitive populations, and candidate/principal studies for hazard evaluation and RfD/RfC derivation.

If so requested, the contractor will document the details that support preliminary decisions regarding potential critical endpoints, MOA, sensitive populations, and candidate/principal studies.

The EPA WAM will communicate detailed requirements by Technical Directions when this Task is undertaken, and will provide examples from recent assessment documents.

Deliverables: Spreadsheet worksheets and Word tables; supporting narrative and appendices when requested
Due Dates:

Drafts with supporting materials, date to be specified in written technical direction.
Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.
Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	**Schedule** (*all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days* after receipt of this PWS
2. Data Entry and QA	To be specified in written technical direction. If not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12 distinct endpoints, or (c) one working day for every 8 distinct studies.
3. Noncancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
4. Cancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
5. Time-to-Tumor Modeling	To be specified in written technical direction. EPA will not require completion of more than 6 data sets per work day (to include data entry and QA, data analysis, and reporting) except by prior agreement with the contractor
6. Draft Materials for IRIS Tox. Reviews	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA
7. Study and Endpoint Screening	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Project Officer (PO)

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Revely-Wilson.Melissa@epa.gov

EPA Work Assignment Manager (WAM)
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Courier Deliveries:
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One Potomac Yard South, 11th Floor S-11225, 2733 S. Crystal Drive, Arlington, VA 22202

EPA Alternate Work Assignment Manager (Alt-WAM)
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-07

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2018 To 04/30/2019	SWG support for IRIS
	Base Option Period Number 4	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2017 To 04/30/2019

Comments:
This amendment is to do a no cost extension from 10/31/2018 to 4/30/2019 and to add Jeff Gift as the Work Assignment Manager. All other terms and conditions remain unchanged.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2018 To 04/30/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Jeff Gift (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-4828
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-10

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2018	Pb Rulemaking
	Base Option Period Number 4	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2017 To 10/31/2018

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2018		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Charles Bevington (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-8814 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 4-10

TITLE: Finalizing Materials on Lead (Pb) Regulatory Assessments and Supplemental Exposure Support

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Specify Section & Paragraph SOW: Please select from the following: D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search

PERIOD OF PERFORMANCE: CO award to 10/31/18

I. PURPOSE

The primary purpose of this work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) (hereinafter EPA or Agency) Office of Pollution Prevention and Toxics (OPPT), in the completion of the analyses that support lead regulatory efforts for the following projects:

- Public and Commercial Buildings
- Lead Hazard Standard
- Residential Opt-Out

A secondary purpose of this work assignment is to provide supplemental exposure support to OPPT for the following projects:

- Development or refinement of any model or approach, including documentation, developed for lead that also has utility for assessments of other chemical substances
- Targeted support for components of exposure assessment for existing chemicals other than lead.

II. BACKGROUND

EPA is undertaking rulemakings intended to revise certain provisions of the Lead Renovation Repair and Painting (LRRP) Rule and to cover public and commercial buildings not covered by the LRRP rule. Under previous work assignments, the contractor provided support for many activities including the following:

- Developing an approach for estimating the residential dust hazard standards that would achieve each of four alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative. This was reviewed by the SAB in July 2010
- Refining the approach for estimating the residential dust hazard standards that would achieve each of the three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change associated with each alternative. The contractor estimated blood lead concentrations in children under age 6 using methods based on specific epidemiology papers.
- Developing an approach for estimating the dust hazard standards for interior renovations in P&CBs that would achieve each of three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative dust hazard standard. The contractor developed an approach for estimating certain cardiovascular effects in adults for each alternative dust hazard standard.
- Refining the approach for estimating hazard standards in residences and P&CBs after a second review by the SAB in December 2010.

- Development of an Approach to estimate benefits from exterior renovations of P&CBs that contain lead paint. Blood lead estimates were estimated using the IEUBK model and IQ changes were estimated for young children. This Approach document was completed in 2012 but was not released because of a settlement agreement which combined exterior and interior renovations for P&CBs.
- Development of an Approach to estimate benefits from exterior and interior renovations of P&CBs that contain lead based paint. Blood and bone lead estimates were estimated using an updated version of the Leggett model and IQ changes were estimated for children 0-10 while cardiovascular disease mortality, reduced kidney function, and low birth weight health outcomes were estimated for adults. This Approach document was completed and released on August 6, 2014.
- The Approach document was then peer reviewed and a peer review report was received on February 27, 2015.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. This work assignment will require contractor staff to be thoroughly familiar with the IQ change analysis that was performed for the 2008 LRRP final rule. That rule and directions to its support materials may be found at http://www.epa.gov/lead/pubs/renovation.htm. Contractor staff with expertise in pharmacokinetic modeling of lead, biostatistics for lead, and computer modeling for lead are essential for this work assignment.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved. The contractor shall not perform any computer modeling work under this work assignment until the quality assurance statement is reviewed and approved by the WAM and the OPPT QA Manager.

Task 3: Complete Exposure and Health Analyses for Ongoing Lead Regulatory Projects
Task 3a: Public and Commercial Buildings Documentation

The contractor shall complete updates to the Approach document to be called: **"Approach taken to Estimate Exposures and Incremental Health Effects from Lead due to Renovation, Repair, and Painting Activities in Public and**

Commercial Buildings." The document and its supplementary files shall document changes from the August 2014 Approach and provide response to peer review. Delivery of the Approach Document and its supplemental files is expected to be iterative with drafts submitted monthly. The final report is anticipated to have 10 chapters within the Approach document and 6 supplemental files. The contractor shall document versions carefully, incorporate comments from EPA, to determine when a chapter and/or supplemental file moves from draft to final status. Note, finalization of the "results" chapter is contingent upon finishing task 3b.

Task 3b: Public and Commercial Buildings Modeling

All model inputs have been refined and revised in previous option years with the exception of model inputs dependent upon results of survey. Within the option period, EPA expects results from an industry survey to become available. The last step of the public and commercial buildings analysis will be to update model inputs as needed based on survey feedback, refine scenarios, and re-run the deterministic and Monte Carlo model so that those results can be incorporated into the results chapter under 3a.

Task 3c: Update Lead (Pb) Dust Hazard Standard Approach Documentation

The contractor shall complete updates to the Approach document to be called: **"Approach taken to Estimate Lead Dust Hazard Standards."** This report shall refine information from the 2010 and 2011 Hazard Standard documents, peer review feedback, and consolidate into one updated document incorporated results of the literature search conducted under work assignment 3-10.

The contractor shall complete a report summarizing the dust lead to blood lead relationship with specific values for lead dust, correlated with specific blood lead readings. The report shall include tables showing the lead loading to blood lead relationship across a continuous spectrum of data points. The report shall describe the "empirical" and "mechanistic/modeling" approach and associated trade-offs related to uncertainty and variability inherent in these approaches.

Task 3d: Update Lead (Pb) Dust Hazard Standard Modeling

The contractor shall complete any exposure and blood lead modeling associated with developing candidate dust hazard standard levels. The modeling should be done after consultation with EPA workgroup to define required modeling inputs and associated decisions. It is understood that dust concentrations are required to run blood lead models. The contractor shall document model input parameters, and data sources that are used by all versions of models used, and identify opportunities to make these parameters identical and/or identify reasons why the parameters may be different between the models. The contractor shall update the input file values for different parameters to match.

The analysis should assume contributions to dust separately from contributions of other lead-sources such as soil, drinking water, and ambient air. Dust lead loadings will be presented in units of $\mu g/ft^2$, soil concentrations will be presented in units of parts per million (ppm), and blood lead levels will be communicated in units of $\mu g/dL$.

Task 3e: Exposures of Opt-Out Provision for Residential Repair and Painting re-analysis

On April 22, 2010, EPA issued a Final Rule revoking the opt-out provision of the 2008 RRP Rule. The Rule was published in the Federal Register on May 6, 2010, and took effect on July 6, 2010. As originally published in 2008, the RRP Rule allowed homeowners to "opt out" of the requirement to hire a trained renovator who follows the RRP work practices if the homeowner certifies that (1) the renovation will occur in the owner's residence, (2) no child under age 6 or pregnant women resides there, (3) the housing is not a child-occupied facility, and (4) the owner acknowledges that the renovation firm will not be required to use the work practices

contained in the RRP Rule. Under the 2010 RRP Rule, homeowners are no longer permitted to "opt out" of having a renovation performed without the RRP work practices.

Some variation of the opt-out provision may be restored. Variations of the opt-out and associated changes in exposures, blood lead, and IQ for those exposure scenarios would be assessed. For example, restoring the 2008 opt-out, opt-out only for post-1960 housing, opt-out only for interior residential renovations, opt-out only for non-prohibited practices, or other variations yet to be determined. The scenarios associated with these options would be given to the economists to determine associated trade-offs of benefits/health and cost.

Task 4: Develop, update, or refine Exposure Models or Databases used for Lead and applicable for other chemicals

Under previous work assignments, the contractor has developed a wide range of exposure models that could be further repurposed and documented for use with chemicals other than lead. Examples of models developed include the Fortran version of the All Ages Lead Model, applications of AERMOD for deposition, a soil and hard surface model, and an Indoor Dust Model. Examples of database include generic building layouts for building categories, monitoring and biomonitoring data, blood lead data, and data related to lead-safe work practices. The contractor shall, upon receipt of technical direction, further develop stand-alone graphical user-interfaces and model documentation through user guides. No more than two GUIs would be requested in the option year and EPA will follow up with technical direction prior to initiation of model development.

Task 5: Targeted support for components of exposure assessment for existing chemicals other than lead.

The contractor shall provide targeted support for components of exposure assessment for existing chemicals other than lead. These exposure support activities are not an entire exposure assessment. Instead, they may encompass targeted modeling from one source/use to one environmental concentration or further characterization of a range of potential doses from a set of environmental concentrations. For planning purposes, the contractor may assume no more than 8 requests for targeted exposure support activities within the period of performance.

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Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award
Task 3a: Public and Commercial Buildings Report	Monthly deliverables starting end of December until complete
Task 3b: Public and Commercial Buildings Modeling	Monthly deliverables starting end of December until complete
Task 3c: Hazard Standard Report	Monthly deliverables starting end of December until complete

Task 3d: Hazard Standard Modeling	Monthly deliverables starting end of December until complete
Task 3e: Opt Out Residential RRP	Monthly deliverables starting end of December until complete
Task 4: Model development and documentation	Within 1 month of receipt of technical direction
Task 5: Targeted Exposure Support for chemicals other than Lead	Within 1 month of receipt of technical direction

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

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2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

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(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

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The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):
Charles Bevington
OPPT-RAD AB2
Bevington.charles@epa.gov
202-564-8814

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-10

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 04/30/2019	Pb Rulemaking
	Base Option Period Number 4	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2017 To 04/30/2019

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 04/30/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Charles Bevington (Signature) (Date)		Branch/Mail Code: Phone Number: 202-564-8814 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)		Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 4-10

TITLE: Finalizing Materials on Lead (Pb) Regulatory Assessments and Supplemental Exposure Support

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Specify Section & Paragraph SOW: Please select from the following: D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search

PERIOD OF PERFORMANCE: CO award to 10/31/18

I. PURPOSE

The primary purpose of this work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) (hereinafter EPA or Agency) Office of Pollution Prevention and Toxics (OPPT), in the completion of the analyses that support lead regulatory efforts for the following projects:

- Public and Commercial Buildings
- Lead Hazard Standard
- Residential Opt-Out

A secondary purpose of this work assignment is to provide supplemental exposure support to OPPT for the following projects:

- Development or refinement of any model or approach, including documentation, developed for lead that also has utility for assessments of other chemical substances
- Targeted support for components of exposure assessment for existing chemicals other than lead.

II. BACKGROUND

EPA is undertaking rulemakings intended to revise certain provisions of the Lead Renovation Repair and Painting (LRRP) Rule and to cover public and commercial buildings not covered by the LRRP rule. Under previous work assignments, the contractor provided support for many activities including the following:

- Developing an approach for estimating the residential dust hazard standards that would achieve each of four alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative. This was reviewed by the SAB in July 2010
- Refining the approach for estimating the residential dust hazard standards that would achieve each of the three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change associated with each alternative. The contractor estimated blood lead concentrations in children under age 6 using methods based on specific epidemiology papers.
- Developing an approach for estimating the dust hazard standards for interior renovations in P&CBs that would achieve each of three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative dust hazard standard. The contractor developed an approach for estimating certain cardiovascular effects in adults for each alternative dust hazard standard.
- Refining the approach for estimating hazard standards in residences and P&CBs after a second review by the SAB in December 2010.

- Development of an Approach to estimate benefits from exterior renovations of P&CBs that contain lead paint. Blood lead estimates were estimated using the IEUBK model and IQ changes were estimated for young children. This Approach document was completed in 2012 but was not released because of a settlement agreement which combined exterior and interior renovations for P&CBs.
- Development of an Approach to estimate benefits from exterior and interior renovations of P&CBs that contain lead based paint. Blood and bone lead estimates were estimated using an updated version of the Leggett model and IQ changes were estimated for children 0-10 while cardiovascular disease mortality, reduced kidney function, and low birth weight health outcomes were estimated for adults. This Approach document was completed and released on August 6, 2014.
- The Approach document was then peer reviewed and a peer review report was received on February 27, 2015.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. This work assignment will require contractor staff to be thoroughly familiar with the IQ change analysis that was performed for the 2008 LRRP final rule. That rule and directions to its support materials may be found at http://www.epa.gov/lead/pubs/renovation.htm. Contractor staff with expertise in pharmacokinetic modeling of lead, biostatistics for lead, and computer modeling for lead are essential for this work assignment.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved. The contractor shall not perform any computer modeling work under this work assignment until the quality assurance statement is reviewed and approved by the WAM and the OPPT QA Manager.

Task 3: Complete Exposure and Health Analyses for Ongoing Lead Regulatory Projects
Task 3a: Public and Commercial Buildings Documentation

The contractor shall complete updates to the Approach document to be called: **"Approach taken to Estimate Exposures and Incremental Health Effects from Lead due to Renovation, Repair, and Painting Activities in Public and**

Commercial Buildings." The document and its supplementary files shall document changes from the August 2014 Approach and provide response to peer review. Delivery of the Approach Document and its supplemental files is expected to be iterative with drafts submitted monthly. The final report is anticipated to have 10 chapters within the Approach document and 6 supplemental files. The contractor shall document versions carefully, incorporate comments from EPA, to determine when a chapter and/or supplemental file moves from draft to final status. Note, finalization of the "results" chapter is contingent upon finishing task 3b.

Task 3b: Public and Commercial Buildings Modeling
All model inputs have been refined and revised in previous option years with the exception of model inputs dependent upon results of survey. Within the option period, EPA expects results from an industry survey to become available. The last step of the public and commercial buildings analysis will be to update model inputs as needed based on survey feedback, refine scenarios, and re-run the deterministic and Monte Carlo model so that those results can be incorporated into the results chapter under 3a.

Task 3c: Update Lead (Pb) Dust Hazard Standard Approach Documentation
The contractor shall complete updates to the Approach document to be called: **"Technical Support Document: for Residential Dust-Lead Hazard Standards."** This report shall refine information from the 2010 and 2011 Hazard Standard documents, peer review feedback, and consolidate into one updated document incorporated results of the literature search conducted under work assignment 3-10.

The contractor shall complete a report summarizing the dust lead to blood lead relationship with specific values for lead dust, correlated with specific blood lead readings. The report shall include tables showing the lead loading to blood lead relationship across a continuous spectrum of data points. The report shall describe the "empirical" and "mechanistic/modeling" approach and associated trade-offs related to uncertainty and variability inherent in these approaches.

The contractor shall refine and finalize the Technical Support Document used to support EPA's proposed rulemaking to lower its dust-lead hazard standard.

Task 3d: Update Lead (Pb) Dust Hazard Standard Modeling
The contractor shall complete any exposure and blood lead modeling associated with developing candidate dust hazard standard levels. The modeling should be done after consultation with EPA workgroup to define required modeling inputs and associated decisions. It is understood that dust concentrations are required to run blood lead models. The contractor shall document model input parameters, and data sources that are used by all versions of models used, and identify opportunities to make these parameters identical and/or identify reasons why the parameters may be different between the models. The contractor shall update the input file values for different parameters to match.

The analysis should assume contributions to dust separately from contributions of other lead-sources such as soil, drinking water, and ambient air. Dust lead loadings will be presented in units of $\mu g/ft^2$, soil concentrations will be presented in units of parts per million (ppm), and blood lead levels will be communicated in units of $\mu g/dL$.

If available, the contractor shall integrate modeling completed by others in EPA's Office of Research and Development to characterize dust-factor based ingestion rates, thus avoiding the loading to concentration relationship, and the SHEDS-IEUBK modeling.

Task 4: Develop, update, or refine Exposure Models or Databases used for Lead and applicable for other chemicals

Under previous work assignments, the contractor has developed a wide range of exposure models that could be further repurposed and documented for use with chemicals other than lead. Examples of models developed include the Fortran version of the All Ages Lead Model, applications of AERMOD for deposition, a soil and hard surface model, and an Indoor Dust Model. Examples of database include generic building layouts for building categories, monitoring and biomonitoring data, blood lead data, and data related to lead-safe work practices.

Task 4A: The contractor shall, upon receipt of technical direction, further develop stand-alone graphical user-interfaces and exposure model documentation through user guides. No more than two GUIs would be requested in the option year and EPA will follow up with technical direction prior to initiation of model development.

Task 4B: The contractor shall use blood lead modeling expertise to integrate, document, and finalize guides for the All-Ages Lead Model-Fortran. This includes building a graphical user interface to iterate the model. A sensitivity analysis is also requested to summarize key choices made in model input parameterization for upcoming SAB review.

Task 5: Targeted support for components of exposure assessment for existing chemicals other than lead.

The contractor shall provide targeted support for components of exposure assessment for existing chemicals other than lead. These exposure support activities are not an entire exposure assessment. Instead, they may encompass targeted modeling from one source/use to one environmental concentration or further characterization of a range of potential doses from a set of environmental concentrations. For planning purposes, the contractor may assume no more than 8 requests for targeted exposure support activities within the period of performance.

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Task 4a: Model development and documentation	Within 1 month of receipt of technical direction
Task 4b: AALM-Fortran documentation, GUI, and sensitivity analysis	Within 2 months of receipt of technical direction
Task 5: Targeted Exposure Support for chemicals other than Lead	Within 1 month of receipt of technical direction

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Appendix A

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After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

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VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

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Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-13

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2018	EPA-Expo-Box
	Base Option Period Number 4	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2017 To 10/31/2018

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2018 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 4-13

TITLE: Technical Support for Revisions to EPA-Expo-Box (a toolbox for exposure assessors)

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: CO approval through 10/31/2017.

I. PURPOSE.

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) for revisions to EPA-Expo-Box (a toolbox for exposure assessors). This is a continuation of efforts conducted under work assignment 4-77 of contract number EP-C-09-009 and work assignments 0-13, 1-13, 2-13, and 3-13 of contract number EP-C-14-001.

II. BACKGROUND AND OBJECTIVES.

EPA-Expo-Box is an online toolbox for exposure assessors. It was developed by EPA's Office of Research and Development, National Center of Environmental Assessment (NCEA) to serve as a web-based compendium of exposure assessment tools. It is comprised of a series of Tool Sets, each containing modules that address exposure assessment topics. Toolbox modules contain descriptions of the topics and links to exposure assessment resources including databases, models, guidance documents, and other resources for exposure assessors. A search interface allows users to identify resources using keywords or topics. EPA-Expo-Box was originally released in Fall 2013 and a revision in the new Drupal format was released in 2015. Periodic maintenance of the Toolbox will be necessary to ensure that EPA-Expo-Box content and tool links remain current. Technical assistance will be required for updating EPA-Expo-Box as needed.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of five tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

Deliverable 1: The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

Task 2. The contractor shall assist in correcting broken links in EPA-Expo-Box.

The contractor shall conduct a maximum of 2 comprehensive reviews of the links in EPA-Expo-Box to identify and correct any broken links **at intervals to be designated by the COR in written technical direction. Within 2 weeks of receiving technical direction from the COR,** the contractor shall suggest replacement links for broken links and/or links to outdated tools. A record of these changes shall be maintained by the contractor using the tracking spreadsheet maintained under work assignments 0-13, 1-13, 2-13, and 3-13 of the contract.

Deliverable 2a: The contractor shall conduct a maximum of 2 comprehensive reviews of the links in the Master Tool List **at intervals to be designated by the COR in written technical direction.**

Deliverable 2b: The contractor shall provide replacement links for broken links and/or links to outdated tools **within 2 weeks of receiving technical direction from the COR.**

Task 3. The contractor shall assist in addressing comments on EPA-Expo-Box.

The contractor shall assist EPA in addressing comments/questions received on EPA-Expo-Box, as needed. The contractor shall prepare and submit to the COR draft responses **within 1 week after receiving comments/questions from the COR**. For the purpose of preparing the work plan and cost estimate for this work assignment, the contractor shall assume that, if any, only minor comments/questions will be received. The contractor shall also assume that if revisions to the toolbox are needed, they will be minor. The list of comments/questions and their resolution that was maintained under work assignments 0-13, 1-13, 2-13, and 3-13 of this contract shall continue to be maintained in order to track revisions made to the Toolbox.

Deliverable 3: The contractor shall prepare and submit responses to the comments/questions, and any proposed changes to the toolbox, **within 1 week of being assigned by the COR**.

Task 4. The contractor shall assist in updating EPA-Expo-Box content

Revisions to EPA-Expo-Box may occasionally be needed to reflect updated EPA exposure assessment policies or procedures. Based on technical direction from the COR, the contractor shall identify specific areas within EPA-Expo-Box that will require revision and provide suggested changes to the Toolbox. For the purposes of this cost estimate, the contractor shall assume that, if any, only minor revisions will be required. The contractor shall provide the COR with a list of suggested revisions **within 2 weeks of receiving technical direction from the COR regarding the necessary revisions.**

Deliverable 4: The contractor shall provide the COR with a detailed list of suggested revisions **within 2 weeks after receiving technical direction from the COR.**

Task 5. The contractor shall provide information to update the Master Tool List

A Master Tool List for EPA-Expo-Box was developed previously under work assignment 4-77 of contract EP-

C-09-009 and updated under work assignments 0-13, 1-13, 2-13, and 3-13 of EP-C-14-001. The contractor shall provide the necessary information to revise and update the Master Tool List, as needed, to correct broken links (Task 2), to incorporate any new tools that have been identified from comments/questions on the Toolbox (see Task 3), and to add tools based on the revision of existing content (Tasks 4). The contractor shall ensure that any new or updated tools have been appropriately assigned to the various Tool Sets, modules, and sub-modules (many of the tools will be applicable in more than one module or sub-module), and that accurate tool descriptions and key words are provided. The contractor shall submit all of the draft information necessary to revise and update the Master Tool List to the COR **within 2 weeks after completing Tasks 2, 3, and 4** for comment by the COR. **Within 1 week after receiving comments from the COR**, the contractor shall submit the final information necessary to update the Master Tool List.

Deliverable 5a: The contractor shall submit to the COR draft information necessary to revise and update the Master Tool List **within 2 weeks after completing Tasks 2, 3, and 4.**

Deliverable 5b: The contractor shall submit the final information necessary to update the Master Tool List to the COR **within 1 week after the receipt of the COR's comments on Deliverable 5a**.

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

.IV. TIME TABLE.

Task	Deliverable	Time frame
1a	Establish communication via conference call	Within 1 week after receipt of work assignment
2a	Review Toolbox links	At intervals to be designated by COR
2b	Provide replacement links	Within 2 weeks of receiving technical direction from the COR
3	Prepare responses to issues or topic areas	Within 1 week of being assigned by COR
4	Submit revised content	Within 2 weeks of being assigned by COR
5a	Submit draft information for Master Tool List	Within 2 weeks after completing Tasks 2, 3, and 4
5b	Submit final information for Master Tool List	Within 1 week of COR comments

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).

3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.

4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the

contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager
Linda Phillips
US EPA (8623P)
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
Telephone #: (703) 347-0366
FAX #: (703) 347-8690
Email: phillips.linda@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-13

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2017 To 10/31/2018 Base Option Period Number 4	Support for EPA-Expo-Box

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2017 To 10/31/2018

Comments:
This amendment is to add Maureen Johnson as the Alt. COR. All other terms and conditions remain unchanged.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2017 To 10/31/2018		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Linda Phillips (Signature) (Date)		Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)		Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-13

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 04/30/2019 Base Option Period Number 4	Support for EPA-Expo-Box

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2017 To 04/30/2019

Comments:
This amendment is to add an additional hours and to extend the period of performance to 4/30/19.
All other terms and conditions remain unchanged. See attached Amended PWS.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 04/30/2019		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee	LOE:
Cumulative Approved:		Cost/Fee	LOE:

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	703-347-0366
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William M. Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-14

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2018 Base Option Period Number 4	Development of Tool for Microb

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2017 To 10/31/2018

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
This Action:	11/01/2013 To 10/31/2018		
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee	LOE:
Cumulative Approved:		Cost/Fee	LOE:

Work Assignment Manager Name: Erin Silvestri (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-569-7619
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 4-14
Option Year 4
AMENDED 04/17/17

TITLE: Development of a Tool for Microbiological Data Usability for Environmental Decision Making

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Erin Silvestri, Work Assignment Manager (WAM)
Kathy Hall, Alternate WAM

HSRP Partner Need: 2017-B16. Biological Data Usability: Development of best practices for biological agent data quality objectives, data interpretation, and data utilization/extrapolation of field-collected samples characterized by semi-quantitative laboratory methods (e.g. culture and PCR).

Period of Performance: November 1, 2017 – October 31, 2018

I. OBJECTIVES

The main objective of this Work Assignment (WA) is to support continued development and completion of the U.S. Environmental Protection Agency (EPA) tool for determining data usability requirements needed for environmental data collection and analysis of microbial samples for decision making. The tool will provide microbial data collectors, analyzers, and decision makers a standardized basis for developing sampling and analysis plans while simultaneously documenting data quality objectives to ensure the required quality and quantity of environmental data is sufficient to support remedial decisions.

II. BACKGROUND

The EPA-NHSRC was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, the EPA-NHSRC's Threat and Consequence Assessment Division (TCAD) is responsible for assessing potential exposures associated with the intentional release of hazardous and toxic materials including chemical, biological, and nuclear threat agents. TCAD is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of the TCAD is the applications of microbial environmental assessment methodologies utilized to support cleanup decision making regarding cleanup goals, treatment technology efficacies, and detection limits during biological contamination incidents.

The EPA developed the Guidance for Data Usability in Risk Assessment Parts A and B (U.S. EPA, 1992a and 1992b) to offer guidance for chemical (Part A) and radionuclides (Part B) data collection and analysis. However, there is currently no similar guidance for microbial samples

available for the EPA responders and managers who lead the site data collection or for the personnel who must interpret the data analysis for the site decision makers. This tool incorporates considerations for data quality into development of a sampling and analysis plan and is a stepping stone to filling these gaps.

III. TASKS

Task 1: Work plan development and modification of the Quality Assurance Project Plan (QAPP) as Needed

Task 1a: Work Plan Development:

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the Work Assignment Manager (WAM)/Alternate Work Assignment Manager (Alternate-WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The contractor shall generate a workplan that follows on work completed in the previous three performance periods, describing how tasks 2-5 shall be performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations.

Within the workplan, the contractor shall deliver to the EPA WAM/Alternate WAM a Project Management file outlining the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships.

Task 1b: QAPP Modification

The contractor shall modify the existing QAPP as necessary to implement any changes to planning, implementing, and assessing the effectiveness of its quality assurance and quality control procedures for the continued development and implementation of an online tool and related tasks per any changes in this option year PWS. The QAPP should incorporate a test plan to outline how the task shall be conducted and the measures taken to ensure data quality using the appropriate practices. If the existing QAPP is sufficient to cover the work under 4-14, then an updated signature page will be signed to reflect that the content is still applicable.

Attachment 1 to the Performance Work Statement (PWS) or Statement of Work (SOW) provides information regarding **NHSRC QA Requirements/Definitions List.** Attachment 2 to the Performance Work Statement (PWS) details the **QA for software and data management projects**.

QAPPs prepared for a Category B (formerly known as a Category 3 or 4) project must be developed in accordance with the document titled "EPA Requirements for Quality Assurance Project Plans." EPA QA/R-5 can be found at https://www.epa.gov/sites/production/files/2016-06/documents/r5-final_0.pdf and must be approved by an EPA Quality Assurance Manager (QAM) prior to the start of any literature searches (existing data), data collection, gathering, synthesizing, or data generation (laboratory) work.

At the discretion of the Contract Officer Representative (COR), a Category B QAPP may be based on the R5 guidance (described above) or a NHSRC project-specific QA requirements template provided as Attachment 2.

Additional information related to QA requirements can be found at www.epa.gov/quality.

The contractor is responsible for the quality of the work, data and/or measurements of any potential subcontractors. The process the contractor shall use for assessment of quality standards and measurements performed by any subcontractor shall be addressed in the QAPP.

The contractor shall provide QAPP document preparation and revision(s) as well as maintaining any additional quality assurance paperwork, including required SOP or records of work performed. The contractor shall ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. The contractor shall ensure that this documentation is maintained in an appropriate fashion, and make this documentation available for inspection by the EPA WAM/Alternate WAM, the EPA Quality Assurance Manager (QAM) or others as designated by these individuals. All supporting documentation shall be referenced and attached to the QAPP.

Deliverable: Conference Call and Project Management file

Performance Standard: The contractor shall provide the draft workplan containing projected *tasks' specifics requested within 30 days of award.*

Deliverable: Modified QAPP

Performance Standard: If modification of the QAPP is required, the contractor shall provide the draft of the modified QAPP containing all required elements mentioned above within 30 days of award. If modification is not required, an updated signature page will be signed indicating that the existing QAPP fulfills the contract work.

Task 2: Data Usability Tool for Microbial Samples Working Group Meetings

The contractor shall organize, manage, and summarize up to 2 virtual technical working group meetings. In addition, travel for up to 1 two day face to face meeting is optional under this WA. For each meeting:

1. The contractor shall work with the EPA WAM/Alternate WAM to determine a schedule for the meetings.
2. Each virtual meeting will be no more than 2 hours in length. If the optional face to face meeting is conducted, the meeting shall be no more than two days in length. The contractor will work with EPA to develop each meeting agenda and meeting location.
3. The contractor will assist EPA in meeting facilitation.
4. The contractor will provide up to 4 ICF personnel to support the meeting efforts as determined by the agenda.
5. EPA will be responsible for virtual meeting logistics and workgroup member notifications.
6. The contractor shall provide draft meeting summaries documenting discussion by the workgroup members to the EPA WAM/Alternate WAM. Upon approval of the EPA WAM/Alternate WAM the meeting summaries will be sent to the workgroup members by EPA. The meeting summaries will be included a decision table and an action item table. Draft meeting summaries will be revised by the EPA.
7. Any comments/recommendations received by the EPA outside of the meetings will be sent to ICF by the WAM/Alternate WAM to be included in the agenda for the next meeting.

Deliverable: Technical expert workgroup meeting facilitation and meeting summary reports

Performance Standard: The contractor shall facilitate virtual (and optional face to face) meetings and provide draft meeting summaries to EPA within one week following the meeting.

Task 3: Online Data Usability Tool for Microbial Samples in Decision Making

Task 3a: Microbial Data Usability Tool Revisions

1. The contractor shall revise and update the draft online tool based off of the expert working group input and WAM comments received during and after the technical meetings, in response to Beta Test comments (beta test conducted under 3-14) and per revisions requested by the EPA WAM.
2. The contractor shall provide scientific and technical support under the direction of the EPA WAM/Alternate WAM for the development of this product.
3. The contractor shall review revisions of the tool with the EPA WAM. Upon approval of the WAM, the revised tool will be sent through NHSRC clearance.
4. It is expected that final tool production will be completed by the end of this contract period.

Task 3b: Web Hosting Conference Calls

1. The contractor shall participate in EPA Information Technology (IT) related conference calls to provide information on the Microbial Data Usability Tool and contribute to technical discussions in preparation for hosting the tool on the EPA website.
2. It is anticipated that there will be up to 10 one-hour calls which will be set up by EPA.
3. It is anticipated that up to two (2) ICF staff will participate on each call.

Task 3c: Microbial Data Usability Tool User's Guide Document (Optional)

1. The Contractor shall provide revisions and a final draft of the Microbial Data Usability Tool User's Guide document.
2. Content revisions will be determined by the EPA WAM based on information generated by the workgroup.
3. After approval of the workgroup, the companion document will undergo, as applicable, up to 4 cycles of document review requiring coordination, collection of comments, preparation of response to comment documents, resolution of comments with EPA WAM/Alternate WAM, and updating the draft document based on received and accepted comments, and preparing final documents including formatting, document cover development, and 508 compliancy.

Task 3d: Support with Revisions of Tool in Response to Clearance Comments

1. The contractor shall provide revisions to the tool in response to comments provided during the NHSRC clearance process.
2. As applicable, this may include up to 4 cycles of tool review requiring coordination, collection of comments, preparation of response to comment documents, resolution of comments with EPA WAM/Alternate WAM, and updating the draft tool based on received and accepted comments, and preparing the final tool for production.
3. The tool should be fully functional for this stage of the review.

Task 3e: Transfer of Tool to EPA

1. The contractor will provide the means to transfer of the tool to be hosted on the EPA server.
2. The contractor shall also provide all development files, planning documents, and code via a disk or other physical media.
3. The contractor shall develop a checklist of files or hardware to be used to operate and host the tool, and upon receipt of the that content, provide a check to ensure everything is there.

Deliverable: Final fully functional MicroSAP web-based tool

Performance Standard:

Tool: 1) The contractor shall revise the microbial tool within 1 month after final comments have been provided by the EPA.

Web Hosting Conference Calls: The contractor will participated in web hosting conference calls as outlined in Task 3b.

Clearance of Tool: 1) The contractor shall provide revisions and response to comments on the tool for each of the 4 review cycles within 3 weeks of receiving the comments. 2) The contractor shall provide a final viable product within 1 month after final clearance of the tool.

Code Transfer: The contractor shall provide transfer of the final tool, disk with tool files, and checklist within 1 month of final clearance of the tool.

***Deliverable: User's Guide (*Optional)**

Performance Standard: Deliverables and schedule will be determined when requested by EPA.

Task 4: Communications and Progress Reports

Monthly contract conference calls: Shall be conducted between the EPA WAM/Alternate WAM and the contractor to keep EPA-NHSRC updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work including notable milestones met, issues (including quality assurance issues) and resolutions, and path forward including anticipated timing for completion of WA goals. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures), a table of current and cumulative level of effort and cost expenditures by task, and a graph of the actual and projected obligations and expenditures for the current fiscal year.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to EPA-NHSRC. EPA-NHSRC shall provide comments back to the contractor after which the contractor shall provide a revision back to EPA WAM/Alternate WAM with responses and dispositions of comments. Required reviews for the final tool and the final companion document or any reports which will be made publically available will undergo, as applicable, up to 4 cycles of review as discussed in Task 3d.

All references cited in submitted reports and deliverables to EPA-NHSRC shall be provided to EPA-NHSRC in pdf format.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and of quality as outlined in the QAPP. All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to EPA-NHSRC. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by EPA-NHSRC, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software as agreed to by the EPA WAM/Alternate WAM. The literature resources shall be provided in a compatible electronic format, such as EndNote. The contractor shall provide a CD containing all data and documentation for the tool. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Monthly contract conference calls, monthly reports, and periodic meetings as needed.

Performance Standard: The contractor shall participate in monthly contract conference calls and other meetings as needed and submit monthly reports.

IV. PERFORMANCE PERIOD

The performance period is 12 months from the date of award.

V. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Deliverables:

Task	Deliverable	Due date
1	Work Plan	Per contract requirements
	Modified QAPP	Draft 30 days after contract award, updated as necessary thereafter.
2	Data Usability Tool for Microbial Samples Working Group Meetings facilitation	• Support for up to 2 virtual meetings and 1 face to face meeting as directed by EPA • Provide meeting summaries to EPA within one week after each meeting unless otherwise agreed to by EPA.
3	Microbial tool revisions	Within 1 month after the final comments are provided by the EPA
	Clearance revisions and comment response	Within 3 weeks of receiving comments from each review cycle
	Final product for production	Within 1 month of tool clearance
	Web Hosting Conference Calls	As directed by EPA
	Microbial Data Usability Tool User's Guide	(Optional): Deliverables and schedule will be determined when requested by EPA.
	Tool Code Transfer	Within 1 month of final tool clearance
4	Monthly contract conference calls and periodic meetings	As directed by EPA
	Monthly reports	Per contract requirements

QUALITY ASSURANCE SURVEILLANCE

Task	Output	Performance Standard	Monitoring Method
1	Modified QAPP	QAPP is approved by EPA-NHSRC QA.	EPA receives QAPP per contract requirements. Revisions and comment resolution for all QA comments are provided to EPA within 2 weeks of receipt of notification of comments by EPA WAM/Alternate-WAM.
1	Work Plan	Contractor shall provide the completed workplan within 30 days of award.	Work plan is provided to EPA per contract requirements. Revisions to work plan are completed per contract requirements.
2	Working Group Meetings	Contractor shall assist in the facilitation of technical working group meetings and develop the associated meeting summaries.	**Technical Effort:** The Contractor shall abide by the WA QAPP in performing services and providing the support on this task. **Timeliness:** Services and deliverables shall be in accordance with schedules stated in the WA, unless amended or modified by an approved EPA action.
3	Tool Revisions; User's Guide; Code Transfer	The products will be technically correct and meet the quality assurance standards as outlined in the QAPP. All technical issues related to development will be resolved.	**Technical Effort:** The Contractor shall abide by the WA QAPP in performing services and providing the support on this task. **Timeliness:** Services and deliverables shall be in accordance with schedules stated in the WA, unless amended or modified by an approved EPA action.
4	Communications and Progress Reports	Monthly conference calls between ICF and EPA WAM/Alternate WAM Monthly Reports	Services and deliverables shall be in accordance with schedules stated in the WA, unless amended or modified by an approved EPA action. Monthly reports meet the standards as set up in the approved work plan.

VI. INTELLECTUAL PROPERTY

All methods, models and tools developed by the contractor and/or provided to the contractor under this WA is the intellectual property of the EPA-NHSRC. All data collected and analyzed under this WA is the intellectual property of the EPA-NHSRC.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent of real personal or organizational conflict of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT CONTRACT OFFICER TECHNICAL REPRESENTATIVE (WAM)

Erin Silvestri (WAM)
Threat and Consequences Division
National Homeland Security Research Center
U.S. EPA Office of Research and Development
Work: (513) 569-7619
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26 W. Martin Luther King Drive (NG-16)
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Kathy Hall (Alternate-WAM)_

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Cincinnati, OH 45268

Attachment # 1
NHSRC QA
Requirements/Definitions List

EPA's Quality System Website: http://www.epa.gov/quality
EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html
EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address

requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at http://www.epa.gov/quality/QS-docs/g5m-final.pdf..

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A

QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
CRADA	Cooperative Research and Development Agreement
IA	Interagency Agreement
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA	Quality Assurance
QA ID	Quality Assurance Identification
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
QS	Quality System
SOW	Statement of Work
TLP	Technical Lead Person

ATTACHMENT 2

QAPP REQUIREMENTS FOR SOFTWARE AND DATA MANAGEMENT PROJECTS

Types of projects to which this guidance applies include the following: software development, software/hardware systems development, data base design and maintenance, and data validation and verification systems. The QAPP requirements for software development in this appendix do not mandate a particular method for software development. Project managers should choose software development and QA methods best suited to their individual projects within the parameters set forth here. Table D-1 provides a set of alternative QAPP elements for situations in which the elements applicable to measurement projects are not appropriate. The applicability of different elements is based on (1) the QA category and (2) the size or complexity of the task. Projects that involve both measurement and software/systems development should have plans addressing all applicable QA elements. Main issues to consider for inclusion in a QAPP for software and data management are listed in the following sections.
Additional guidance for software and data management projects is available from the QAMs.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

SECTION 1.0, PROJECT DESCRIPTION

This section should provide an overview of the project, its intended uses, quality objectives, schedules and appropriate milestones, information about the hardware and operating systems, and planning documents.

SECTION 2.0, PROJECT ORGANIZATION AND RESPONSIBILITIES

This section should discuss all important intramural and extramural project personnel and should show the relationship between the development team and the personnel responsible for QA and testing.

SECTION 3.0, FUNCTIONAL REQUIREMENTS

This section should provide a list of the most important functions that the software system must address. This section can also state any quantitative or qualitative data quality objectives (DQOs) that might apply to the software.

SECTION 4.0, SYSTEM DESIGN OVERVIEW (HIGH LEVEL DESIGN)

A brief description of the system design is all that is necessary in the QAPP, if additional design documentation is planned.

SECTION 5.0, DETAILED DESIGN

Complex projects and those with significant defensibility requirements should have a detailed design document.

SECTION 6.0, IMPLEMENTATION

Written standard operating procedures (SOPs) for software development should be provided for extremely large and complex software projects. The internal checks applied during development should also be described.

SECTION 7.0, TESTING

The QAPP should outline the testing strategy to be used.

SECTION 8.0, DATA VALIDATION AND VERIFICATION

The QAPP must describe the means for checking the correctness of outputs.

SECTION 9.0, CHANGE CONTROL AND CONFIGURATION MANAGEMENT

This section should describe the procedures for controlling and documenting all significant changes to software and hardware.

SECTION 10.0, AUDITS AND REVIEWS

This section should describe planned assessments, including performance evaluation audits (PEAs), technical systems audits (TSAs), quality systems audits (QSAs), and audits of data quality (ADQs). Additional types of reviews applicable to these projects include peer reviews and beta testing.

SECTION 11.0, MAINTENANCE AND USER SUPPORT

Where software or data generated by the project will be distributed outside NHSRC, maintenance and user support must be addressed.

SECTION 12.0, SYSTEM DOCUMENTATION AND ARCHIVING

Documentation is required for software projects in all QA categories. Table D-2 gives documentation requirements by QA Category.

SECTION 13.0, QA PROGRESS REPORTS TO MANAGEMENT

System development QA and QC results and plans should be reported regularly, particularly in projects in Category A and where contractually required.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-14

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 04/30/2019 Base Option Period Number 4	Development of Tool for Microb

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2017 To 04/30/2019

Comments:
Per ICF email dated 8/13/18: This will be at no additional cost to the project. We have adjusted resources on several tasks and had developers working on the project with a lower hourly rate than the developers

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 04/30/2019		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Erin Silvestri (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7619 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number: